

Message

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**Subject:** OCSPP News for November 25, 2020

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### Plastics Used By Auto Sector to Get EPA Chemical Risk Probe

Pat Rizzuto, Bloomberg Law

<https://news.bloomberglaw.com/environment-and-energy/plastics-used-by-auto-sector-to-get-epa-chemical-risk-probe>

ExxonMobil, Evonik, Teknor Apex sought evaluation  
Both chemicals widely used in auto, other industries

The EPA proposed Wednesday to examine whether two chemicals used to make plastics for the automobile and other industries are too risky for people's health or the environment.

The Environmental Protection Agency released for public comment its draft plans to evaluate industrial, commercial, and consumer uses of diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP). The agency, under the 2016 Toxic Substances Control Act amendments, would have to regulate their uses if they pose unreasonable risks.

DIDP and DINP belong to a family of chemicals called phthalates and are commonly used as plasticizers in the production of plastic and plastic coatings to increase flexibility.

The ExxonMobil Chemical Co., working through the American Chemistry Council's (ACC) High Phthalates Panel, asked the EPA to evaluate some of DIDP's uses. ExxonMobil, Evonik Corp., and Teknor Apex, also working through ACC's panel, asked the agency to evaluate DINP's uses.

Using a formula set by TSCA and an accompanying regulation, all three companies are paying for half the cost of the EPA's analysis. The draft risk evaluation plans, called scopes, don't say what their fee will be.

### **Environmentalists Ask EPA To Expand 1,4-Dioxane Peer Review, Comment**

Maria Hegstad, Inside TSCA

<https://insideepa.com/tsca-news/environmentalists-ask-epa-expand-14-dioxane-peer-review-comment>

Environmentalists are pressing EPA to conduct a second peer review and expand a short public comment window on its controversial supplement to the agency's draft TSCA evaluation on 1,4-dioxane, which found no unreasonable risks from a host of new consumer uses the agency evaluated, which would preempt looming state action on the chemical if finalized.

In a Nov. 23 letter to exiting toxics chief Alex Dunn, the groups charge that failing to grant a 40-day public comment extension and additional peer review by the Science Advisory Committee on Chemicals (SACC) would violate the agency's rules and key statutes.

They also charge that the abbreviated review schedule is unfair, given that the agency recently granted an industry request to extend the comment deadline on a revised draft assessment the agency issued under the Toxic Substances Control Act (TSCA) for pigment violet 29 (PV29) -- which strengthened the agency's initial findings -- even though PV29 has fewer uses and effects far fewer people than dioxane.

The groups argue that the supplement presents entirely new analyses since EPA released its first draft evaluation in June 2019, and as such should undergo peer review and extended public scrutiny.

"The supplement represents a major expansion in the scope of the 1,4-dioxane risk evaluation. EPA has for the first time evaluated consumer exposures, adding eight conditions of use involving types of consumer products in which 1,4-dioxane is present as a byproduct," states the letter, from groups including Safer Chemicals Healthy Families, Earthjustice, Environmental Defense Fund, Environmental Working Group, Natural Resources Defense Council, and North Carolina Black Alliance, among others.

"EPA has also for the first time evaluated general population exposures to ambient water via recreational swimming and fish consumption."

But the group says this is the first time that EPA has provided only 20 days for public comment on a TSCA evaluation. "This abbreviated comment period is without precedent for TSCA risk evaluations," the letter states. "A 20-day comment period would violate EPA's risk evaluation rule, as well as the provisions of TSCA and Administrative Procedures Act requiring a minimum of 30 days for public comment."

EPA released Nov. 19 its expanded draft evaluation of 1,4-dioxane, one of the first 10 substances under evaluation since Congress reformed TSCA in 2016 that agency officials have pledged to evaluate by the end of the year.

The chemical is widely used as a stabilizer for chlorinated solvents, as well as in building materials, degreasers, and to make soaps and detergents, among other uses. The new draft supplement finds the presence of the chemical as a byproduct in eight consumer products poses no unreasonable risks that must be regulated under TSCA and also that 1,4-dioxane in surface waters used for recreation poses no risk.

The chemical's presence as a byproduct stems from ethoxylation, a process used to make the products less harsh, which leaves 1,4-dioxane as a byproduct in soaps, detergents and other consumer products.

A final decision from EPA that the chemicals present no unreasonable risk would, under TSCA, preempt states from regulating it under the conditions of use the agency evaluated.

### State Preemption

As such, the expansion and draft conclusions represent a win for consumer product manufacturers who had urged EPA to expand the evaluation to preempt pending state rules as states like California and New York have been working to regulate the presence of 1,4-dioxane as a byproduct in consumer products.

As a result, the agency's draft findings drew quick praise from industry groups, such as the Consumer Brands Association (CBA), which along with the American Cleaning Institute asked EPA in July 2019 to expand the draft evaluation to assess such risks.

"The EPA's supplemental evaluation on 1,4 dioxane proves that that agency can be nimble when a state patchwork of policies begins to emerge," says Mike Gruber, CBA's vice president of regulatory and government relations.

But the environmentalists note that EPA's conclusions "are controversial and depart from other assessments, for example, those of New York and California who are in the process of restricting 1,4-dioxane in consumer products."

"Because these consumer products are widely used, millions of Americans are impacted by EPA's supplemental evaluation. If, as we believe, EPA has significantly understated risks to these consumers, the draft evaluation would fail to result in sufficient protections of public health. And if an effect of the evaluation is to preempt state regulation under section 18 of TSCA, consumers would be denied alternative means of protection," their letter says.

They also point to the contrast with EPA's approach to its issuance earlier in the month of a second draft evaluation of PV29, another of the first group of 10 chemicals EPA has pledged to evaluate under TSCA by the end of the year.

"We note that just last week EPA granted a request from the chemical industry for an extension of the public comment period for the agency's draft risk evaluation for Pigment Violet 29. When it released that supplemental draft on October 30, 2020, EPA provided a 30-day comment period, 10 days longer than the period it has now afforded for 1,4-dioxane. EPA has now granted a 20-day extension for PV29, providing a total of 50 days to file comments. PV-29 has narrower uses and impacts a far smaller population than 1,4-dioxane. Given the importance and complexity of the supplemental evaluation for this substance, we request a 40-day extension, resulting in a total comment period of 60 days, the minimum amount of time required by EPA's TSCA regulations for comment on a risk evaluation."

The groups also note that EPA is concurrently conducting a letter peer review of the second PV29 draft, another way in which EPA's approach to 1,4-dioxane differs.

"EPA's decision to dispense with peer review for the supplemental evaluation, again in contrast to PV29, is irresponsible and further compromises the credibility of the Agency's eleventh hour change of course on this important chemical. The earlier SACC report on the initial draft evaluation was highly detailed and made numerous recommendations for improvement. Now that EPA has broadened the scope of the evaluation to include ambient water and consumer

product exposures affecting a broad segment of the US population, further peer review is essential to assure protection of public health. The prior work of the SACC puts it in a strong position to provide EPA with informed and knowledgeable feedback."

### Industry's Interests

An environmentalist attorney tells Inside TSCA that EPA's differing approaches to the two assessments mirror industry's interests.

"The difference here ... is that in the case of PV29, industry is trying to put on the brakes now because they don't like what EPA did," in the second PV29 draft, which newly found several uses of PV29 present unreasonable risk.

"In the case of 1,4-dioxane, they are pushing as hard as they can on the accelerator because they got what they wanted, and they want it finalized."

The source notes that even if California or New York were able to finalize their regulations on 1,4-dioxane before EPA finalizes its risk evaluation, those state regulations "would probably still be preempted although there might be some workarounds under TSCA."

The source notes that under section 18(a)(1)(B), states are barred "from adopting or continuing to enforce" their own regulations on a use of a chemical for which EPA finalizes a no unreasonable risk finding.

The agency did not, however, evaluate exposure via drinking water, in keeping with similar scoping decisions the Trump EPA has made on the other first 10 evaluations. As a result, the final evaluation would not preempt states from regulating 1,4-dioxane in drinking water.

"EPA's decision leaving "out drinking water [is] consistent with its position across all the evaluations that drinking water is covered is by the Safe Drinking Water Act, and is not going to be addressed under TSCA," the attorney says. "However, this approach is inconsistent with the decision to address surface water discharges in the supplemental evaluation since these discharges, like drinking water, are subject to another environmental law but not being regulated. Both drinking water and surface water should be included in the evaluation." -- Maria Hegstad ([mhegstad@iwpnews.com](mailto:mhegstad@iwpnews.com))

### **Groups Urge NCI To Bolster Warnings Of Chemicals' Breast Cancer Risks**

Diana DiGangi, Inside TSCA

<https://insideepa.com/tsca-news/groups-urge-nci-bolster-warnings-chemicals-breast-cancer-risks>

Backed by a former top federal scientist, health and environmental groups are urging the National Cancer Institute (NCI) to bolster data for health care providers and others on its website warning of the scientific link between environmental exposures to toxic chemicals and cancer, particularly breast cancer.

The institute's "patient and health professional Physician Data Queries (PDQ) about breast cancer prevention significantly underrepresent a key piece of breast cancer prevention: reducing breast cancer risk related to environmental exposures," the groups say in a Nov. 17 letter to NCI Director Norman Sharpless.

As a result, the groups ask NCI to implement "a more complete approach to describing breast cancer risk linked to environmental exposures and to explain multidisciplinary scientific approaches for identifying risk factors for complex, multifactorial and long-latency diseases like breast cancer," the letter says.

The letter was signed by dozens of prominent health researchers and other experts, along with 48 health and environmental groups, including the Sierra Club, the Center for Biological Diversity, and Breast Cancer Action, which led the effort.

Breast Cancer Action says on its website that NCI has already agreed to revise its patient prevention information to more clearly explain the evidence that environmental exposures to chemicals are a risk factor for breast cancer. "This is a great first step -- but there's more work to be done," the group adds.

Among the prominent researchers signing the letter are Linda Birnbaum, former director of the National Institute for Environmental Health Sciences and the National Toxicology Program, and Margaret Kripke, professor emerita at MD Anderson Cancer Center and a former member of the President's Cancer Panel.

In a Nov. 21 op-ed in Stat, a health news service, Birnbaum and Kripke reiterate their calls for NCI to bolster its information on chemical exposure and cancer risk.

"NCI is the de facto arbiter of what is considered valid cancer science in this country -- its website should reflect that," wrote Birnbaum and Kripke. "By not sharing the existing research on links between exposure to certain chemicals and breast cancer, it creates an information void that gives policymakers, health care providers, health advocates, cancer patients, and the public the impression that there is no problem."

In their op-ed, Birnbaum and Kripke refer to their break with the NCI on this issue as "unprecedented," saying that "by ignoring the science on breast carcinogens, the NCI puts all women at risk, especially women of color and low-income women."

"That is why we are taking the unprecedented step of breaking our silence and joining more than 100 individuals and organizations to publicly ask the NCI to take action," they write.

"Both of us have been, and continue to be, strong supporters of the National Cancer Institute, but with thousands of lives at stake, we can no longer remain silent."

They add that they believe "sharing this research would reshape the national approach to prevention-oriented public health policy for breast cancer and beyond by acknowledging the importance of evidence from studies in animals and cells as a tool to identify chemical hazards and reduce exposure to them," and that this would be only the beginning of attempts to get the NCI to publicize this kind of information for all cancers.

## Cancer Prevention

The groups' push for NCI to bolster its approach coincides with a similar call from health and business groups for increased regulation of toxic chemicals in paint, solvents, and other substances to help prevent the spread of childhood and other cancers.

"Although changes have been made to the federal [TSCA], these will not drive improvements quickly or broadly enough to shift how things are made for the US market. Further action is needed, and states are addressing the gap by creating their own policies and acting as a backstop for safety; this is critically important as many federal regulations are being eroded," the groups said in their Sept. 23 report, "Childhood Cancer: Cross-Sector Strategies for Prevention."

In their recent letter, the health groups detail five requests, starting with calling for NCI's screening and prevention editorial board to include toxicologists and environmental epidemiologists with expertise in breast carcinogenesis. While NCI has already agreed to this, the groups say this would provide "critical perspectives to help extend the content of both the patient and health professional PDQs," which are fact sheets for medical professionals and patients that provide an overview of risk factors for a type of cancer, as well as possible interventions.

NCI's current patient PDQ for breast cancer notes older age, personal history of breast cancer or benign (noncancer) breast disease, inherited risk of breast cancer, dense breast tissue, reproductive history resulting in greater exposure to estrogen, hormone therapy for symptoms of menopause, radiation therapy to the breast or chest, obesity, and drinking alcohol as risk factors that can make women more likely to develop breast cancer.

Below that, the PDQ currently states that “it is not clear whether” hormonal contraceptives or environmental factors affect the risk of breast cancer.

The groups also called for the board to “regularly update the NCI breast cancer PDQs to reflect new research related to environmental links to the disease.”

They also urged NCI to use risk-based warnings about chemical exposure in its PDQs; to “make clear delineations in the patient breast cancer PDQ of breast cancer risk factors that are modifiable and not modifiable”; to broaden the sources of information in the PDQs to include sources like the National Toxicology Program (NTP) and International Agency for Research on Cancer (IARC); and to “meet with some of the signatories of this letter, including advocates and researchers, to develop an action plan for implementing solutions to these requests.”

“By NCI’s own standards your agency is underrepresenting concerns about environmental links to breast cancer,” the Nov. 17 letter says. “The NCI website states that ‘While increased risk for some cancers is caused by inherited genetic factors (about 5%--10% of cancer cases), most cancers are caused by environmental and lifestyle factors.’” -- Diana DiGangi (ddigangi@iwpnews.com)

### **EPA to host carbon tetrachloride risk management webinar**

Inside TSCA

<https://insideepa.com/tsca-takes/epa-host-carbon-tetrachloride-risk-management-webinar>

EPA is preparing to discuss possible options for regulating unreasonable risks identified in the agency’s recently released final TSCA evaluation of the chemical carbon tetrachloride (CCl<sub>4</sub>), which found that 13 of 15 conditions of use pose unreasonable workplace risks that must be regulated.

The webinar is scheduled for Dec. 10, a week after the Small Business Administration’s (SBA) Office of Advocacy is set to host an environmental roundtable on Dec. 4, dedicated to an EPA briefing on the CCl<sub>4</sub> evaluation and its potential effects on small businesses.

“EPA will host a webinar to educate stakeholders on the risk management process under the Toxic Substances Control Act (TSCA) and the findings in the final risk evaluation for [CCl<sub>4</sub>],” EPA announced Nov. 24. “The webinar also provides the opportunity for the public to provide input on considerations the agency should take into account for managing these unreasonable risks.”

EPA released its final evaluation of CCl<sub>4</sub>, a solvent and feedstock used to produce a host of other chemicals, on Nov. 3. The final version finds that 13 of 15 conditions of use the agency evaluated pose unreasonable workplace risks that must be regulated, including domestic manufacturing, importation, processing, recycling, multiple industrial and commercial uses as well as disposal. Those findings represent a change from the draft version, which identified only four uses that pose such risks. EPA says the unreasonable risks include cancer and liver toxicity from chronic exposures.

EPA’s draft assessment, released last January, found CCl<sub>4</sub> did not pose unreasonable risk to directly exposed workers or the environment, though it may pose unreasonable risk for those workers it calls “occupational non-users (ONUs)” of the chemical. These workers “do not directly handle carbon tetrachloride but perform work in an area where carbon tetrachloride is present,” EPA says.

The changes in the agency’s final conclusions appear to have been driven in part by officials’ agreement in this case to drop its assumption that certain workers and ONUs do not face unreasonable risks because they used personal protective equipment as required by worker safety rules issued by the Occupational Safety and Health Administration.

The evaluation is the fourth of the first batch of 10 evaluations since Congress rewrote TSCA in 2016 that the agency has completed. Top EPA officials are promising to complete the remaining six evaluations by the end of the year, though the agency has since released draft revisions for public comment to two additional risk evaluations among that group, increasing the unlikelihood that EPA will meet its deadline.

## **US EPA outlines potential scope of manufacturer-requested TSCA reviews for DIDP, DINP**

Terry Hyland, Chemical Watch

<https://chemicalwatch.com/184381/us-epa-outlines-potential-scope-of-manufacturer-requested-tsca-reviews-for-didp-dinp>

The US EPA has published draft scope documents for its industry-initiated TSCA risk evaluations of the phthalates diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP).

Like the final scope documents released for 20 high-priority chemicals earlier this year, the draft scopes for DIDP and DINP identify the conditions of use, hazards and exposures the agency plans to consider in its risk evaluations. The final versions will make clear which uses of these high-molecular weight phthalates could become subject to federal regulations if they are found to present an unreasonable risk, but also that will be protected from certain state-level actions.

Releases of the draft scopes follows a June 2019 notice from the EPA that it had received requests from manufacturers represented by the American Chemistry Council's High Phthalates Panel (ACC HPP) to conduct risk evaluations on DIDP and DINP – both of which appear in the TSCA work plan.

That panel said at the time that industry has "full confidence" in the safety of the two common plasticisers, and saw a manufacturer-requested risk evaluation as a path for boosting consumer confidence in their use.

In December 2019 the EPA granted the requests, beginning a three-year risk evaluation that will see it examine whether the substances present an 'unreasonable risk' to human health or the environment.

Comments on the draft scope documents will be accepted for 45 days from their formal publication in the Federal Register.

### **DIDP draft scope**

DIDP is primarily used as a plasticiser in polyvinyl chloride (PVC) in consumer, commercial, and industrial applications, as well as in automotive, agricultural and consumer products. The draft scope on the substance calls for the EPA to evaluate the following 50 conditions of use:

- two manufacturing applications – domestic manufacture and import;
- 15 processing uses – including recycling, repackaging and its incorporation into formulations, mixtures, reaction products or articles like plasticisers, adhesives and lubricants;
- distribution in commerce;
- six industrial uses – including in abrasives, adhesives and sealants, functional fluids, lubricants and solvents;
- 14 commercial applications – including in automotive care products, building and construction materials, electrical and electronic products, furnishing and cleaning products, arts and crafts and other plastic and rubber products;
- in 11 consumer uses – including in automotive care products, lubricants, adhesives, building construction materials, arts and crafts, and in toys, playground and sporting equipment; and
- disposal.

Excluded from the draft scope of uses to be reviewed are those applications covered by other statutes, including DIDP's use in food packaging materials and in military grade sealing compounds and PVC films used in munitions and cartridges.

### **DINP draft scope**

DINP is also primarily used as a plasticiser in polyvinyl chloride (PVC) in consumer, commercial, and industrial applications, with additional applications in paint, electrical and metal products and other consumer uses. Its draft scope calls for the EPA to evaluate 63 conditions of use:

- two manufacturing applications – domestic manufacture and import;
- 18 processing uses – including as a reactant in plasticisers and the manufacture of rubber products, its incorporation into articles used in toys, textiles and electrical equipment, and its incorporation into formulations, mixtures or reaction products and in repackaging and recycling;
- distribution in commerce;
- five industrial uses – including in adhesives and sealant chemicals, plasticisers and building and construction materials;
- 20 commercial applications – including in automotive care products, building and construction materials, electrical and electronic products, paints and coatings, furniture care products, personal care products, arts and crafts, hydraulic fluids and pigments;
- in 16 consumer uses – including automotive care products, adhesives and sealants, building construction materials, paints and coatings, floor coverings, arts and crafts, in toys, playground and sporting equipment, and paper products; and
- disposal.

DINP's use in food packaging materials is excluded from the draft scope of review.

#### DINP in children's products

Use of DINP in certain children's products is included in the scope, which is consistent with the DINP request submitted by industry.

The industry request specifically called out the substance's "use in PVC for children's toys and childcare articles" as an application it wanted included in the risk evaluation.

According to the manufacturer request, the Consumer Product Safety Commission (CPSC) concluded in 2017 that "DINP in isolation does not pose a risk to children, pregnant women or other susceptible individuals with an adequate margin of safety". The panel, however, voted in October of that year to expand and make permanent an interim ban on the use of DINP in children's products – a decision that is the subject of ongoing litigation brought by the ACC and other groups.

"Although DINP is currently restricted in children's toys and childcare articles, the manufacturers, through the ACC HPP, request that potential DINP exposure of children from toys and childcare articles be evaluated, consistent with the agency's stated concerns in the US EPA 2012 Phthalate Action Plan", said the manufacturer request.

Last year the Environmental Defense Fund (EDF) protested about the proposed inclusion of children's products in the scope, arguing that the intent behind it "appears to be to undermine the CPSC's decision to 'permanently prohibit the use of DINP in children's toys and child care articles at levels greater than 0.1%'".

TSCA does not give the EPA the authority to review decisions made by another agency under a different law, said the EDF in October 2019 comments on the industry risk evaluation request.

Moreover, in its first ten agency-initiated TSCA risk evaluations, the EPA has assumed compliance with other federal and state laws. And while the EDF has "strongly opposed this assumption", if the EPA has applied it to other risk evaluations, "it must do so consistently", it said.

#### Next steps, preemption

Once the EPA finalises the documents, any use covered by the evaluation will be subject to "pause preemption". This provision generally blocks states from imposing new restrictions.

The agency's risk evaluation will seek to determine if evaluated conditions of use pose an unreasonable risk. The EPA then must impose regulations on any concerning application within two years of publication of a final risk evaluation.

Both a final risk management rule and a finding of 'no unreasonable risk' are considered "final agency actions" that preempt state-level chemical restrictions.



Preemption, however, only applies to certain activities, and only for those conditions of use included in the scope of a risk evaluation. There is also uncertainty about how preemption will work in practice.

A recent Maine law banning phthalates in food packaging materials represents the type of chemical restriction that could be subject to preemption, for example. However, that use is currently excluded from the draft scope of the EPA's review, and therefore may be unaffected.

### **New York state prohibits facility from incinerating PFAS-containing firefighting foams**

Chemical Watch

<https://chemicalwatch.com/183679/new-york-state-prohibits-facility-from-incinerating-pfas-containing-firefighting-foams>

New York Governor Andrew Cuomo has signed legislation, restricting the incineration of aqueous film-forming foam (AFFF) containing per- and polyfluoroalkyl substances (PFASs) in cities in the state of a certain size that have a designated environmental justice area.

Restrictions in the new law – signed on 23 November – will focus primarily on the city of Cohoes, a former textile manufacturing hub located 15 miles north of Albany, the state capital. It is the home of the Norlite hazardous waste management facility, which previously had stored, handled and incinerated waste AFFF that contained PFASs. According to the state's Department of Environmental Conservation (DEC), the Norlite facility had previously been authorised to burn AFFF as fuel.

In June, after residents raised concerns of potential PFAS exposure, the DEC ordered the facility to stop incineration of the firefighting foams containing PFASs and initiated a programme to study nearby soil and water samples for potential contamination.

In a statement announcing the signing of the bill (SB 7880B), Governor Cuomo's office said the law "bolsters the department's ongoing response to concerns raised by residents in the city of Cohoes to ensure the environment and community are protected after foam containing PFAS was disposed at the Norlite facility".

The law, which takes effect immediately, also highlights the challenge many states face as they try to address an increasing number of reports of PFAS contamination, while balancing the need for firefighting foams that can effectively suppress hard-to-extinguish flammable liquid fires.

Contamination concerns prompted New York lawmakers to impose statewide restrictions on the use of PFAS-containing firefighting foams last December. They modelled the law on an earlier Washington state measure. Those restrictions were eased somewhat in April, to allow the use of AFFFs to contain fires involving ignitable as well as flammable liquids.

Several other states have also passed laws to restrict or ban the use of PFAS-containing firefighting foams, including California, Colorado, Michigan, Minnesota, New Hampshire and Wisconsin.

AFFF manufacturers also face numerous legal cases over PFAS contamination, with potentially "billions of dollars" in claims.

### **EPA finds known carcinogen poses risk to workers, consumers**

E.A. Crunden, E&E News

[https://www.eenews.net/greenwire/2020/11/24/stories/1063719255?utm\\_campaign=edition&utm\\_medium=email&utm\\_source=eenews%3Agreenwire](https://www.eenews.net/greenwire/2020/11/24/stories/1063719255?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Agreenwire)

EPA has finalized its evaluation for a known carcinogen and concluded it poses an outsize health risk, even as environmental advocates say the assessment should go further.

In its final risk evaluation for trichloroethylene (TCE) released yesterday, EPA found 52 of 54 uses of the chemical pose unreasonable risks to consumers and workers. Those uses include areas like manufacturing and processing, along with numerous industrial and commercial uses. Disposal also poses an unreasonable risk, per EPA.

"These unreasonable risks include potential immunosuppression from acute exposures, and autoimmunity and cancer from chronic exposures," EPA wrote in its summary risk evaluation.

The agency found that two areas do not pose an unreasonable risk — distribution in commerce and consumer use in pepper spray. EPA also determined TCE does not pose an unreasonable risk to the environment.

TCE is associated with numerous health risks including development and immunological issues. The chemical has typically been used as a degreasing solvent, as well as in the manufacture of fluorocarbon refrigerants. It is one of the first 10 chemicals singled out for review under the new Toxic Substances Control Act (TSCA), which was overhauled in 2016. EPA has previously proposed banning TCE in products like aerosol degreasers but has since abandoned those plans under the Trump administration.

The chemical has been mentioned in conversations about Nancy Beck, a former chemical industry lobbyist who has been nominated to lead the Consumer Product Safety Commission. Opponents of Beck's nomination say she worked to block EPA from issuing a TCE ban (E&E Daily, June 17).

EPA's findings largely echo a draft risk evaluation assessment released in February, and critics say the agency has not addressed the problems inherent in that initial document.

Two scientists with the Environmental Defense Fund, Jennifer McPartland and Richard Denison, said in a statement that the final evaluation contains "numerous flaws that severely understate the highly toxic chemical's risks" to multiple groups. They say EPA's evaluation "ignores or downplays" exposure sources and pathways including air, food, groundwater used for drinking water and contaminated sites. The agency has said those risks are addressed through other statutes. Another concern is EPA's reliance on immunological effects, rather than fetal cardiac malformations.

"EPA has again abdicated its responsibility under TSCA to identify and evaluate the risks the chemical presents to the general population as well as communities near industrial sites and other contamination sources," the scientists said.

Denison previously called on EPA to postpone a peer review meeting for TCE in March due to the coronavirus pandemic, arguing that members of the health care workforce would be unavailable to provide input (Greenwire, March 17).

TCE is the fifth of the first 10 chemicals reviewed under TSCA to see a final risk evaluation released. EPA has been running behind schedule on releasing those risk evaluations. EPA released its draft risk evaluation for 1,4-dioxane last week (E&E News PM, Nov. 19).

Following the TCE findings, EPA now has two years to address the unreasonable risks laid out in the evaluation via the rulemaking process.

### **EPA Seeking Public Comment on Cleaning Product Ingredient**

Cleaning & Maintenance Management

<https://www.cmmonline.com/news/epa-seeking-public-comment-on-cleaning-product-ingredient>

The U.S. Environmental Protection Agency (EPA) requests public input on a supplemental analysis to the draft risk evaluation for 1,4-dioxane. After releasing the draft risk evaluation in June 2019, in response to public comments and feedback from peer reviewers, EPA conducted a supplemental analysis to the draft risk evaluation. This supplemental analysis includes eight consumer uses, such as surface cleaners and laundry/dishwashing detergents, where 1,4-dioxane is present as a byproduct. The supplemental analysis also assesses exposure to the general population from 1,4-dioxane in surface water.

This supplemental analysis is a critical part of the regulatory process that EPA is following in determining how the agency will regulate 1,4-dioxane in end-use products such as cleaners under the revamped Toxic Substances Control Act (TSCA). EPA has broad authority under TSCA ranging from banning the chemical outright to imposing use restrictions on the end-use product. This EPA regulatory action under TSCA is part of the growing body of regulation that regulates and, in some cases, bans 1,4-dioxane.

In the supplemental analysis to the draft risk evaluation, EPA preliminarily found “no unreasonable risk to consumers from the eight conditions of use assessed.” The agency also preliminarily found “no unreasonable risks under any of the conditions of use to the general population from exposure to 1,4-dioxane.”

Because these additional conditions of use and exposure pathways were not included in the draft risk evaluation, the agency is providing an opportunity for the public to give input on the supplemental analysis and risk determinations before the risk evaluation is finalized. EPA will accept public comments on the supplemental analysis to the draft risk evaluation for 20 days.

It is important for the cleaning industry to weigh in and comment directly to EPA on this supplemental analysis to the draft risk evaluation so that the agency has the benefit of full and robust information in making its regulatory determinations. Accordingly, we encourage ISSA members to comment directly to EPA and also send their comments to ISSA Director of Government Affairs John Nothdurft at [johnn@issa.com](mailto:johnn@issa.com) by December 4, 2020, for our consideration in possibly submitting comments to EPA.

#### **EPA: Over 90% of species put at risk by common weedkiller**

Marc Heller, E&E News

[https://www.eenews.net/greenwire/2020/11/25/stories/1063719377?utm\\_campaign=edition&utm\\_medium=email&utm\\_source=eenews%3Agreenwire](https://www.eenews.net/greenwire/2020/11/25/stories/1063719377?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Agreenwire)

The widely used weedkiller glyphosate is likely to adversely affect endangered species, but mainly from non-agricultural uses, EPA said today.

In a draft biological evaluation for glyphosate, the environmental agency said the uncertainty and lack of available data about uses in non-farm settings is the main driver of the chemical's risk to a variety of wildlife and critical habitats.

The evaluation is available on the agency's website in a series of documents.

More than 90% of various mammals, bird and invertebrates EPA evaluated are likely to be adversely affected, the agency said, with most of those determinations having moderate evidence. The greatest risk is to aquatic invertebrates, with high risks also to fish, the agency said.

Risks are more moderate for mammals, according to the draft evaluation.

"There have been over 1,000 reported ecological incidents involving glyphosate use for birds, fish, terrestrial invertebrates, and terrestrial plants," EPA said.

The draft evaluation, open to a 60-day public comment period, is part of EPA's periodic review of glyphosate — a process it follows for all pesticides. The document doesn't delve into human health effects such as the ongoing debate about whether glyphosate causes cancer.

It also doesn't discuss limits on glyphosate's use or potential changes to its label restrictions, a step that would come later in the process if agencies determine that risks to species warrant it. The review is part of a revised method EPA has adopted this year for evaluating pesticides' risk to endangered or threatened species, the first step of an interagency consultation.

EPA reapproved glyphosate's registration in an interim decision earlier this year, leading the Center for Biological Diversity to accuse the Trump administration of allegiance to its manufacturer, Bayer/Monsanto.

The administration was "clearly willing to bend over backwards, including disregarding its own guidelines for evaluating cancer risks, to give the industry what it wants," the center said at the time. The Natural Resources Defense Council and Pesticide Action Network North America are among the groups suing EPA to stop the use of glyphosate (Greenwire, March 23).

Glyphosate, widely known by the brand name Roundup, is the most widely used weed killer in the United States, applied regularly to crops such as corn and soybeans that have been genetically modified to tolerate it. Between 2013 and 2018, farmers applied about 280 million pounds to 285 million acres, EPA said.

More than 21 million pounds of glyphosate are applied to non-agricultural sites annually, the agency said. Much of that is at the consumer and residential level, EPA said, a use that's hard for the government to track.

Other popular uses in non-farm settings are along public roadways and in forestry, EPA said.

### **Glyphosate Still Under Review**

Emily Unglesbee, Progressive Farmer

<https://www.dtnpf.com/agriculture/web/ag/crops/article/2020/11/25/glyphosates-effects-endangered-new>

ROCKVILLE, Md. (DTN) -- More changes could be ahead for glyphosate use in the U.S. after the EPA released a draft Biological Evaluation for the herbicide, which scrutinizes the pesticide's potential effect on federally listed endangered species and designated critical habitats.

The agency determined that glyphosate is "likely to adversely affect" 1,676 listed species and 759 critical habitats, the vast majority of the species and habitats it considered. If this draft conclusion is finalized as is, EPA will have to loop in two other federal agencies -- the U.S. Fish & Wildlife Service and the National Marine Fisheries Service -- to figure out how best to protect these species and habitats in its registration decisions for glyphosate.

The agency's work on this evaluation is why all past registration decisions for glyphosate and many other pesticides have remained "interim" decisions. All pesticides are now required to undergo biological evaluations, which determine whether they may affect listed endangered species or habitats, which means any registration decisions in the meantime are not legally complete.

See more on EPA's past glyphosate decisions here:

Ultimately, EPA's draft biological evaluation for glyphosate determined that 93% of the endangered species it considered could be negatively affected by the herbicide, with plants accounting for more than half of them. The rest were mammals, reptiles, fish, amphibians, insects and other invertebrates. The agency also concluded that 96% of the critical habitats it considered could be at risk from the herbicide, as well.

At issue is how widespread glyphosate's use is in the U.S., the agency noted in its executive summary of its draft biological evaluation.

### **EPA's final risk evaluation of trichloroethylene is scientifically flawed and understates risks to workers, the general public and those most susceptible**

Jennifer McPartland & Richard Denison, Environmental Defense Fund Blog

<http://blogs.edf.org/health/2020/11/23/epas-final-risk-evaluation-of-trichloroethylene-is-scientifically-flawed-and-understates-risks-to-workers-the-general-public-and-those-most-susceptible/>

Today the Trump Environmental Protection Agency (EPA) issued its final risk evaluation for trichloroethylene (TCE). It largely tracks the agency's draft document, retaining numerous flaws that severely understate the highly toxic chemical's risks to workers, the general public and those most susceptible to its health impacts.

Among the evaluation's most serious deficiencies is the abandonment of a bedrock principle of chemical risk assessment: that risk estimates be based on the most sensitive health effect. Sadly, the final document retains the unprotective approach the Trump White House forced EPA to adopt, as reported in detail by Elizabeth Shogren of Reveal News.

Exposure to TCE is ubiquitous, coming from ambient and indoor air, vapor intrusion from contaminated sites, groundwater and drinking water wells, and food – yet EPA's evaluation ignores or downplays each of these exposure sources and pathways.

Below we summarize some of the major concerns in EPA's evaluation that we addressed in detail in our comments.

One silver lining: Despite its glaring deficiencies, the risk evaluation did find that the great majority of TCE's conditions of use present unreasonable risks—even as it grossly understated the extent of those risks. As a result, EPA must now proceed to regulate those activities, providing the new Administration an opportunity to rectify the serious problems created by the Trump EPA.

Failure to protect against the most sensitive endpoint, fetal cardiac malformations: EPA's reliance on immune-related endpoints instead of fetal cardiac malformations for its determinations of acute and chronic risk deviates from scientific best practices, defies requirements under the law, ignores longstanding agency policy, and is as much as 500-fold less protective of public health.

EPA now falsely claims that its Science Advisory Committee on Chemicals (SACC) supported this decision (see p. 33 of the final evaluation). In fact, the SACC was conflicted and did not reach consensus on this question. The Executive Summary of the SACC peer review report stated (p. 21) that "the Committee was divided on reliance on fetal heart malformations for risk characterization." And while some committee members supported EPA's decision, others did not (p. 94): "To base unreasonable risks on immunosuppression and not on fetal heart malformations appears to some Committee members (and to some public commenters) to accept less protective concentration levels." Unfortunately, the review panel lacked anyone with specific expertise in cardiac development.

Exclusion of known uses and exposures: EPA has again abdicated its responsibility under TSCA to identify and evaluate the risks the chemical presents to the general population as well as communities near industrial sites and other contamination sources. It did so by excluding from its risk evaluation conditions of use and exposures that are known or reasonably foreseen, including exposures from releases of TCE to air, water, and land – amounting to nearly 3 million pounds annually. EPA has also failed to consider exposure to background levels of TCE.

Underestimation of occupational risks: EPA continues to severely underestimate occupational risks in several major ways: its unsupported assumptions regarding worker use of personal protective equipment in many scenarios; its use of a overly lax cancer risk level for workers that fails to protect them as a vulnerable subpopulation as required by TSCA; and its failure to consider combined exposures of workers from multiple sources.

### **Despite Advice from Science Advisors, EPA Continues To Consider Cardiac Risks of Trichloroethylene**

American Chemistry Council

<https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/Despite-Advice-from-Science-Advisors-EPA-Continues-To-Consider-Cardiac-Risks-of-Trichloroethylene.html>

WASHINGTON (November 24, 2020) – With the release of the final risk evaluation for trichloroethylene (TCE), the Environmental Protection Agency (EPA) has not gone far enough in invalidating the purported risk of fetal cardiac defects (FCDs), which is not supported by the vast majority of available research. The agency continues to reference and

validate a 2003 study about FCDs, which its own advisory panel largely rejected earlier in the year due to scientific flaws in how it was conducted and results that have not been replicated in subsequent studies.

The new evaluation, released by the Office of Chemical Safety and Pollution Prevention (OCSPP) this week was conducted under the Toxic Substances Control Act (TSCA), as amended by Congress in 2016. TCE was one of the first 10 substances to be evaluated under the amended TSCA.

A draft of the TSCA risk evaluation was released in February 2020 and peer reviewed in a virtual meeting the following month by EPA's Science Advisory Committee on Chemicals (SACC), a group of independent scientists selected by the agency to review the draft risk evaluations. At that meeting, the majority of SACC members criticized Johnson et al. (2003), the controversial research study linking FCDs in laboratory rats with exposure to TCE. Numerous SACC members called the Johnson study an outlier, not scientifically sound, and not fit to be included or referenced in the final risk evaluation.

The decision not to use cardiac defects as a basis of EPA's risk determination for TCE was supported by the SACC. In its report to EPA on the TCE draft, the SACC echoed the concerns about the positive cardiac data that had been previously identified, including concerns about past use by EPA of reports of cardiac defects raised by a single laboratory whose work has since been called into question by three superior-quality studies that failed to corroborate the FCD response.

Consequently, the SACC cautioned the agency against characterizing the risks of cardiac defects due to the considerable uncertainty about the end point. Despite this caution, EPA included the unreliable FCD-based toxicity value for future consideration of sensitive subpopulations. In effect, by maintaining the FCD-based toxicity value in the final risk evaluation, EPA has contradicted its previous decision to reject this endpoint as a basis for regulatory decision making.

Furthermore, ACC disagrees with the risk evaluation's characterization of Johnson's data quality as "medium" since numerous SACC members questioned and criticized the structure and process of the study. At the same time, the agency seemingly dismissed the findings from the 2019 Charles River Study, which could not replicate the Johnson study's FCD conclusions despite the agency repeatedly stating that it was "a well-conducted study."

We appreciate the fact that the EPA followed the SACC's advice and did not use Johnson's endpoint in its final evaluation, but we remain disappointed that the agency continues to reference the study.

#### **Rayne Guest, R-Water CEO: An Open Letter to The White House Coronavirus Task Force**

Rayne Guest, R-Water for Cision PR Newswier

<https://www.prnewswire.com/news-releases/rayne-guest-r-water-ceo-an-open-letter-to-the-white-house-coronavirus-task-force-301178573.html>

There is a dirty secret in disinfection; it's rarely done properly. Studies conducted by the Center for Disease Control (CDC) confirm that over 70% of new infections occur in those who are diligent about wearing masks. So where are we falling short? Disinfection.

After lingering in the air, COVID lands on surfaces and survives for relatively long periods of time. We touch these surfaces. We place personal items such as face masks and cell phones on these surfaces. One of our greatest weapons in the fight against COVID and other infectious diseases are disinfectants, and they are being used at a ferocious rate in facilities and homes. However, their efficacy and safety hinges on proper use.

Most of the disinfectants on the EPA's List N have a 10-minute contact time. Contact time is the amount of time a disinfectant must remain thoroughly wet on a surface to be effective. However, the CDC states, "Ideally product users should consider and use products that have a shortened contact time."

And, as for disinfectants with a 10-minute contact time, the CDC has determined, "Such a long contact time is not practical for disinfection of environmental surfaces in a health-care setting because most health-care facilities apply a disinfectant and allow it to dry (~1 minute)."

During an April 2020 briefing, President Trump stated, "And then I see the disinfectant where it knocks [COVID] out in a minute. One minute." This disinfectant exists, is aligned with CDC guidelines, and far exceeds Environmental Protection Agency (EPA) requirements for healthcare-grade disinfection and use against COVID. Its active ingredient is the same compound that white blood cells produce to fight pathogens.

We are compelled to comply with the CDC's recommendations to wear masks and practice social distancing. Why is the EPA contradicting the CDC's long-standing advice by listing 10-minute products on the List N? If considered impractical, the use of 10-minute contact time products should be banned, especially during a global pandemic.

The public is worried about their jobs, keeping their small businesses afloat, their children falling behind in school, and what the future might hold for their loved ones. I have been on the ground floor of the disinfection industry for over a decade. By bringing the following facts to the forefront, I assure you, we cannot only get back to normal, we can get back to better than normal.

"Spray and wipe" is a dangerous myth.

All products have a contact time. Disinfectants with a 10-minute contact time, such as Diversey's Virex 256 are commonly used in hospitals. When these products are not allowed to remain wet on a surface for the full 10-minute contact time, proper disinfection cannot be achieved. Annually, the improper use of disinfectants in hospitals has contributed to over 1.7 million healthcare acquired infections and over 100,000 deaths in the U.S. alone. Unfortunately, these horrific infections and deaths became optional to report during the onset of COVID. They, along with COVID and other infectious diseases, need to be addressed.

Not all disinfectants are created equal.

The public deserves transparency. The EPA requires that healthcare grade disinfectants eliminate at least 95%-98.3% of the pathogen carriers tested in a 10-minute contact time. At least one disinfectant on the market achieves 100% effectiveness in one minute. Lab reports should not be classified as proprietary. Consumers need access to this information so that they can make informed decisions.

Restaurants are not required to use disinfectants effective against COVID.

COVID cases are being linked to restaurants. It seems logical that they would be required to use disinfectants effective against COVID. Fortunately, some establishments, like Dallas steakhouse Al Biernat's, have taken it upon themselves to surpass COVID-19 safety and state sanitation guidelines. They have implemented enhanced protocols and now use a one-minute contact time healthcare-grade disinfectant that is safe for food contact surfaces.

Many Disinfectants contribute to asthma, allergies, and COVID symptoms.

Products like Lysol may not be as gentle or fresh as variety names like For Baby's Room and Fresh Beginnings might lead you to believe. According to the manufacturer, the product contains added fragrances and perfumes, in addition to other chemicals which are known to cause asthma and exacerbate other respiratory issues. They also contain ingredients that are Toxic Air Contaminants and are found on the EPA's list of chemicals we need to make it a priority to eliminate. Disinfectants are pesticides and their hazards should be revealed, not hidden.

Disinfectants produced by EPA regulated devices are not eligible for the List N.

The EPA should be seeking disinfecting products produced by devices that have been tested according to their healthcare grade guidelines and have short contact times. Why? Producing disinfectants on-site has numerous advantages including eliminating supply chain reliance and procurement inefficiencies, ensuring an ample supply of disinfectant is always on hand, and eliminating unnecessary packaging and hazardous plastic waste.

These are confusing times with constantly evolving health and safety guidelines. However, the recommendation that surfaces be disinfected to help prevent the spread of infectious disease has held steady. It is time to do it properly.

Dr. Fauci, you have held the position of Director of the National Institute of Allergy and Infectious Diseases since 1984. When speaking about disinfection, I implore you to move beyond the general rhetoric of "follow the manufacturer's

instructions" and set a global standard for proper disinfecting protocols. It is time to provide the public with practical information and bring to light an archaic industry that has been causing unnecessary harm to human and environmental health for far too long. Global citizens deserve the right to live healthy lives. I would like the opportunity to meet with the White House Coronavirus Task Force and discuss solutions that address these critical issues.

### **EPA Finds Glyphosate Is Likely to Injure or Kill 93% of Endangered Species**

Center for Biological Diversity

<https://biologicaldiversity.org/w/news/press-releases/epa-finds-glyphosate-likely-injure-or-kill-93-endangered-species-2020-11-25/>

WASHINGTON— The Environmental Protection Agency released a draft biological evaluation today finding that glyphosate is likely to injure or kill 93% of the plants and animals protected under the Endangered Species Act.

The long-anticipated draft biological evaluation released by the agency's pesticide office found that 1,676 endangered species are likely to be harmed by glyphosate, the active ingredient in Roundup and the world's most-used pesticide.

The draft biological opinion also found that glyphosate adversely modifies critical habitat for 759 endangered species, or 96% of all species for which critical habitat has been designated.

"The hideous impacts of glyphosate on the nation's most endangered species are impossible to ignore now," said Lori Ann Burd, environmental health director at the Center for Biological Diversity. "Glyphosate use is so widespread that even the EPA's notoriously industry-friendly pesticide office had to conclude that there are hardly any endangered species that can manage to evade its toxic impacts."

Hundreds of millions of pounds of glyphosate are used each year in the United States, mostly in agriculture but also on lawns, gardens, landscaping, roadsides, schoolyards, national forests, rangelands, power lines and more.

According to the EPA, 280 million pounds of glyphosate are used just in agriculture, and glyphosate is sprayed on 298 million acres of crop land each year. Eighty-four percent of glyphosate pounds applied in agriculture are applied to soy, corn and cotton, commodity crops that are genetically engineered to tolerate being drenched with quantities of glyphosate that would normally kill a plant.

Glyphosate is also widely used in fruit and vegetable production.

"As we prepare to feast on our favorite Thanksgiving dishes, the ugly truth of how harmful industrial-scale agriculture has become in the U.S. has never been so apparent," said Burd. "If we want to stop the extinction of amazing creatures like monarch butterflies, we need the EPA to take action to stop the out-of-control spraying of deadly poisons."

The EPA has, for decades, steadfastly refused to comply with its obligation under the Endangered Species Act to assess the harms of pesticides to protected plants and animals. But it was finally forced to do this evaluation under the terms of a 2016 legal agreement with the Center.

Emails obtained in litigation brought against Monsanto/Bayer by cancer victims and their families have uncovered a disturbingly cozy relationship between the agency and the company on matters involving the glyphosate risk assessment.

In one example, when the U.S. Department of Health and Human Services announced it would be reviewing glyphosate's safety, an EPA official assured Monsanto he would work to thwart the review, saying, "If I can kill this, I should get a medal." The Health and Human Services review was delayed for three years.

Monsanto/Bayer has also enjoyed broad support from the Trump White House. A domestic policy advisor in the Trump administration stated, "We have Monsanto's back on pesticides regulation."



Earlier this year, relying on confidential industry research, the EPA reapproved glyphosate. The EPA's assessment contradicts a 2015 World Health Organization analysis of published research that determined glyphosate is a probable carcinogen.

President-elect Joe Biden has already tapped Michael McCabe, a former consultant to chemical giant DuPont, to join his Environmental Protection Agency transition board, drawing broad outrage, including from Erin Brockovich.

#### **EPA Seeks Comment on Supplemental Analysis to Draft Risk Evaluation of 1,4-Dioxane**

Lynn L. Bergeson & Carla N. Hutton, B&C TSCA Blog

<http://www.tscablog.com/entry/epa-seeks-comment-on-supplemental-analysis-to-draft-risk-evaluation-of-14-d>

The U.S. Environmental Protection Agency (EPA) announced on November 20, 2020, the availability of a supplemental analysis to the draft risk evaluation of 1,4-dioxane under the Toxic Substances Control Act (TSCA). 85 Fed. Reg. 74341. EPA states that it developed the supplemental analysis in response to public and peer review comments on the draft risk evaluation. The supplemental analysis includes eight consumer uses, including surface cleaners, laundry/dishwashing detergents, and paint/floor lacquer, where 1,4-dioxane is present as a byproduct. The supplemental analysis also assesses exposure to the general population from 1,4-dioxane in surface water. In the supplemental analysis, EPA preliminarily found no unreasonable risk to consumers from the eight conditions of use assessed. EPA also preliminarily found no unreasonable risks under any of the conditions of use to the general population from exposure to 1,4-dioxane. Comments are due December 10, 2020. More information on the draft risk evaluation of 1,4-dioxane is available in our July 2, 2019, memorandum.

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